



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Even a 1% increase in HDL can significantly enhance support of heart health.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

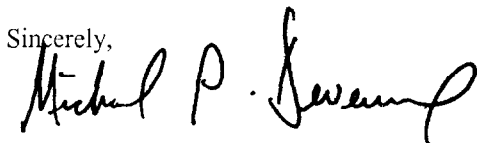
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

0119 6 11-3 00:00

975 0162

LET

17097

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like\**

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	HDL Rx is a physician-developed dietary supplement that has been clinically shown to increase good cholesterol levels, particularly HDL-2, the best form of cholesterol.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY***What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	HDL RX combines essential vitamins and minerals, at levels recommended by the American Heart Association (AHA), with amino acids, powerful antioxidants, and traditional herbal extracts to provide superior support for cardiovascular health.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

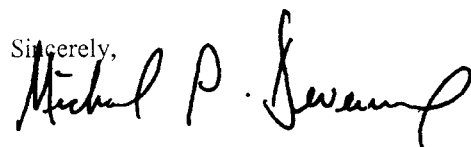
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitamine Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

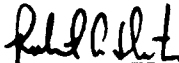
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	By reducing C-reactive protein levels, HDL RX helps support the body's natural anti-inflammatory response.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

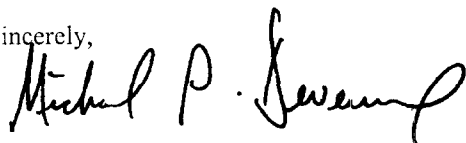
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

**ENZYMATIC THERAPY®**  
&  
**PHYTOPHARMICA®**

## ENZYMATIC THERAPY

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

*What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	The smaller HDL-3 is synthesized by the liver and intestines. This form, which is known as "free cholesterol-rich" HDL, scavenges or "scoops up" free cholesterol. The cholesterol is then chemically altered by the addition of an ester group. When sufficient cholesterol is esterified, HDL-3 becomes HDL-2, which is therefore referred to as "cholesterol ester-rich" HDL. HDL-2 is larger in size and has been shown to be more cardio supportive than HDL-3.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

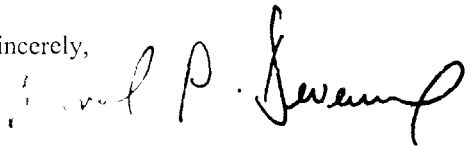
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with a large, stylized "M" and "P".

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

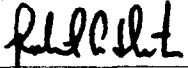
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Both HDL and LDL levels are important indicators of healthy cardiovascular function.* Therefore, supplements that increase the level of good cholesterol can profoundly impact heart health.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

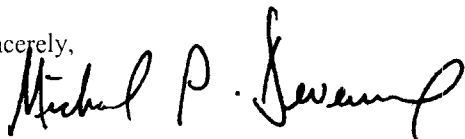
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY***What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	The trial involved 50 people, who were evaluated prior to the study, then again at three and six months. After three months of supplementation, good cholesterol levels increased in all groups.* The changes were more pronounced at the six-month time point, where good cholesterol rose up to 23 percent and levels of HDL-2 (the best cholesterol) increased 50 percent in one subset of participants (HDL <40 mg/dL).* Additionally, the supplement also helped maintain healthy triglycerides levels that were already within the normal ranges.* Decreases in homocysteine, an amino acid found in the blood that plays a role in cardiovascular health, were observed as well.* Therefore, supplements that increase the level of good cholesterol can profoundly impact heart health.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

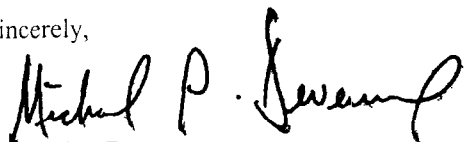
Date: \_\_\_\_\_

12-8-05

HDL RX 21e

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	An antioxidant clinically shown to support the health of the cardiovascular system and increase HDL-2 cholesterol levels.*	Vitamin C (ascorbic acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

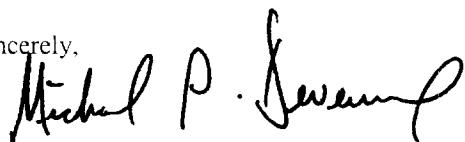
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P 920.469.1313 F. 888.570.6460 (Enzymatic)  
P: 920.469.9099 F. 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	VitaminC provides protection for the inner lining of the arteries.*	Vitamin C (ascorbic acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 8, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

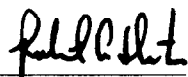
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Another powerful antioxidant, which inhibits the oxidation of low density lipids by inactivating free radicals.* Also, supports healthy cholesterol levels already within the normal range.*	Vitamin E (as natural mixed tocopherols)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

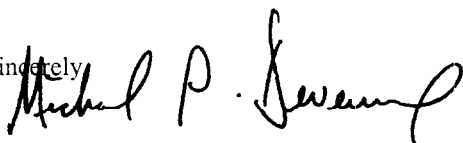
By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-8-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like.™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	An essential coenzyme for normal amino acid metabolism. In particular, Vitamin B6 is necessary for the breakdown of homocysteine, an amino acid that plays a supporting role in cardiovascular health.*	Vitamin B6 (as pyridoxine HCl)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

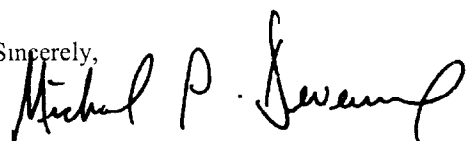
By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	In lipid metabolism, supports normal cholesterol production and metabolism to help retain healthy cholesterol levels that are already within normal limits.*	Niacin (as niacinamide)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By. 

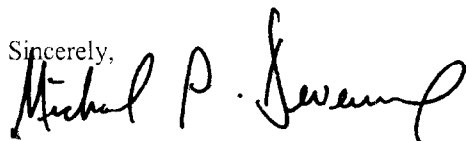
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Increases good cholesterol levels, particularly HDL-2 (the best cholesterol).*	Niacin (as niacinamide)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

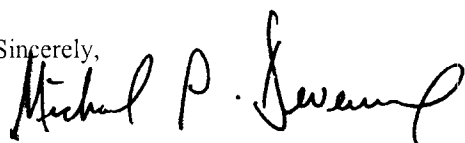
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®**

**&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F 920.469.4418 (Phyto)



**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY***What Better feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Through peripheral vasodilatation, niacin also supports the retention of healthy blood pressure already within the normal range.*	Niacin (as niacinamide)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

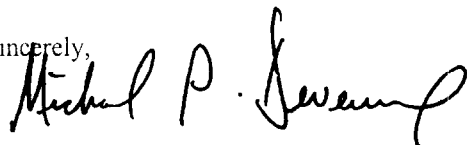
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas    PhytoPharmica  
Tyler Encapsulations    Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386    F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313    F: 888.570.6460 (Enzymatic)  
P: 920.469.9099    F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What Better feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE:    Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	High levels of circulating vitamin B6 have been associated with reduced levels of C-reactive protein, another important indicator of heart health.*	Vitamin B6 (as pyridoxine HCl)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-9-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A homocysteine lower agent, folic acid is essential for the formation of red and white blood cells and involved in the synthesis of certain amino acids.*	Folic Acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

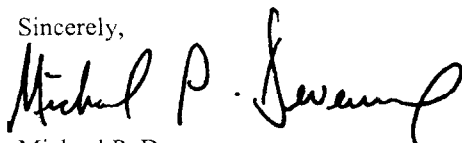
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/9/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582 0467

### ENZYMATIC THERAPY®

&

### PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 9, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A buiquitoud coenzyme necessary for DNA synthesis. Also, lowers homocysteine levels.*	Vitamin B12 (as cyanocobalamin)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

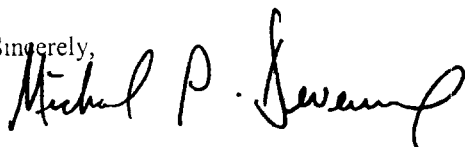
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/9/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE. Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Increases HDL levels, supporting a healthy lipid profile, and helps maintain healthy blood pressure already within the normal limits.*	Magnesium (from magnesium amino acid chelate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

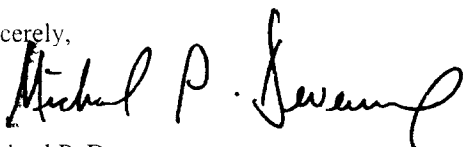
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

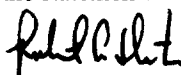
RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	An essential trace mineral with powerful antioxidant capabilities.*	Selenium (as L-selenomethionine)

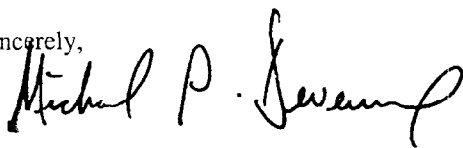
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Research has revealed that selenium supports cardiovascular function.*	Selenium (as L-selenomethionine)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

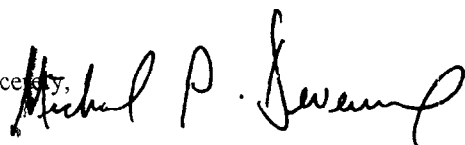
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam,

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	An important amino acid and precursor to nitric oxide (NO), which is important for the health of the cardiovascular, immune, and nervous system.*	L-Arginine (as L-arginine HCl)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

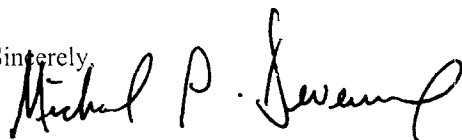
By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer





## ENZYMATIC THERAPY

*What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	In clinical study, an L-arginine-enriched diet increased good cholesterol levels.*	L-Arginine (as L-arginine HCl)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

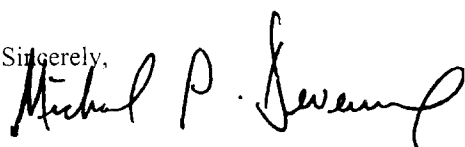
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE. Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Along with coenzyme Q10, L-carnitine is a key factor in metabolism, supporting the production of cellular energy.*	L-Carnitine (as L-carnitine L-tartrate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By.

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date.

12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY® & PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	L-Carnitine is shown to increase good cholesterol (HDL) levels.*	L-Carnitine (as L-carnitine L-tartrate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

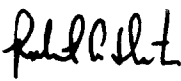
RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	L-Carnitine supports healthy blood flow.*	L-Carnitine (as L-carnitine L-tartrate)

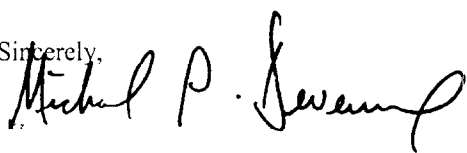
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

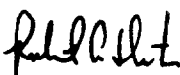
RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A powerful free radical scavenger, clinically shown to support arterial health.*	Coenzyme Q10 (CoQ10) (ubiquinone 10)

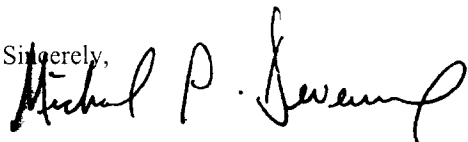
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas    PhytoPharmica  
Tyler Encapsulations    Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386    F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313    F: 888.570.6460 (Enzymatic)  
P: 920.469.9099    F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

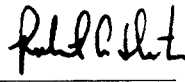
RE:    Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Supplementation significantly improves good cholesterol levels.*	Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

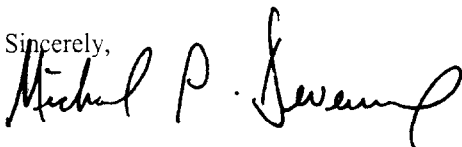
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	CoQ10 supports healthy heart contractility and circulation.*	Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

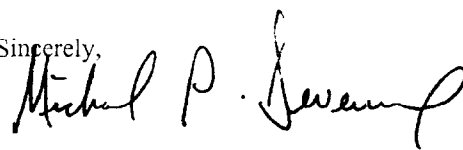
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	In a clinical study, supplementation results in a 14 percent increase in HDL cholesterol over an 8-week period.*	Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

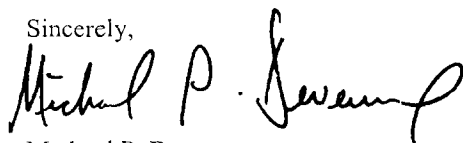
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer





## ENZYMATIC THERAPY

*What **Better** feels like™*

December 10, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

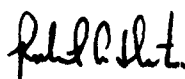
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Helps retain healthy cholesterol levels already within the normal range.*	Hawthorn (Crataegus oxyacantha) Berry Extract

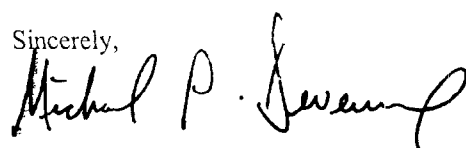
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-10-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  
  
Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Supports the muscle strength of the heart, helping to maintain healthy heart rhythm, contractility, and vascular circulation.*	Hawthorn (Crataegus oxyacantha) Berry Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

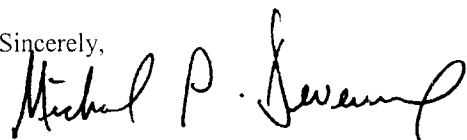
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582 0467

ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469 9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P. 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740


RE Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A source of antioxidant constituents that protect against oxidative damage.*	Hawthorn (Crataegus oxyacantha) Berry Extract

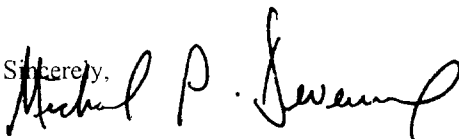
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY***What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Supports the health of veins and arteries.* Also, helps maintain healthy blood pressure levels already within the normal range.*	Hawthorn (Crataegus oxyacantha) Berry Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

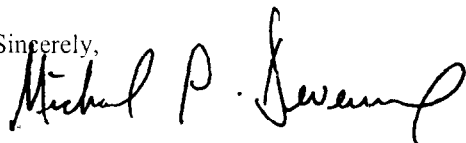
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Taurine possesses both antioxidant and membrane-supportive properties.*	Taurine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740


RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Helps maintain a healthy lipid profile by increasing good (HDL) cholesterol levels.*	Taurine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

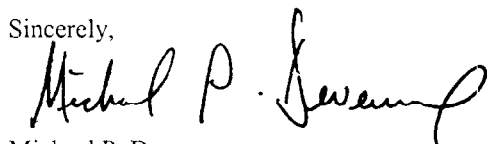
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A powerful antioxidant that possesses wide-ranging cardiovascular health benefits.*	Garlic ( <i>Allium sativum</i> ) bulb

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

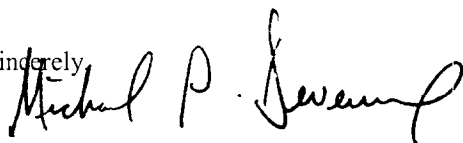
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Clinically shown to increase good cholesterol levels, particularly HDL-2 cholesterol.*	Garlic ( <i>Allium sativum</i> ) bulb

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

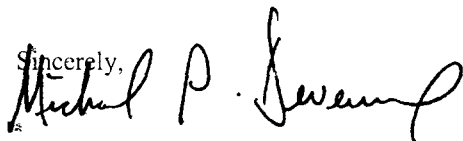
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer





## ENZYMATIC THERAPY

*What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

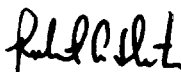
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A source of free-radical scavenging phytonutrients, known as polyphenols.*	Grape Seed (Vitis vinifera) Extract, Grape Skin (Vitis vinifera) Extract

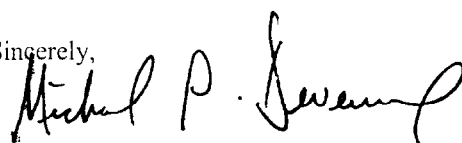
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**INTEGRATIVE THERAPEUTICS INC.\***NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY\*****&  
PHYTOPHARMICA\***

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY***What Better feels like.™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Promotes healthy circulation.*	Grape Seed (Vitis vinifera) Extract, Grape Skin (Vitis vinifera) Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date

12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Supports cardiovascular health by increasing HDL cholesterol levels.*	Grape Seed (Vitis vinifera) Extract, Grape Skin (Vitis vinifera) Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

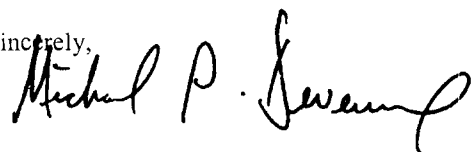
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

What *Better* feels like™

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	A derivative of amino acid, cysteine, NAC is a key intermediary in the conversion of cysteine into glutathione, one of the body's primary cellular antioxidants.*	Acetyl-L-Cysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  
Michael P. Devereux

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

What *Better* feels like™

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

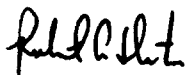
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.


PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Supports the health of the cardiovascular and immune systems.*	Acetyl-L-Cysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Shown to significantly increase HDL cholesterol.*	Acetyl-L-Cysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

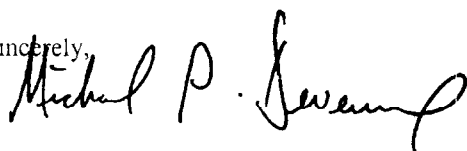
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/12/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Helps maintain healthy blood flow and healthy heart contraction.*	Acetyl-L-Cysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&

### PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

*What **Better** feels like™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Provide antioxidant protection, supporting cardiovascular and immune system health.*	Soy Isoflavones

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer





## ENZYMATIC THERAPY

*What **Better** feels like.™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Soy protein-enriched diet has been shown to support healthy lipid profiles by significantly increasing HDL cholesterol levels.*	Soy Isoflavones

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

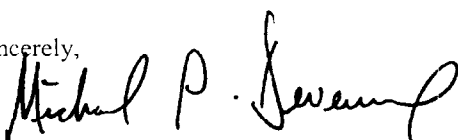
By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  


Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like™*

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Powerful antioxidants that support the health of arteries.* Shown, in clinical study, to support healthy cholesterol levels already within the normal range.*	Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

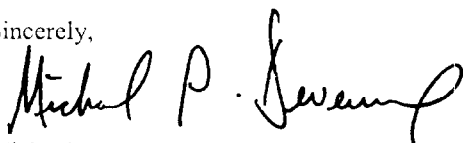
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer



## ENZYMATIC THERAPY

What *Better* feels like™

December 12, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Replaces the CoQ10 depleted by cholesterol lowering (statin) drugs.*	Vitamin C (ascorbic acid), Vitamin E (as natural mixed tocopherols), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Magnesium (from magnesium amino acid chelate), Selenium (as L-selenomethionine), Proprietary Blend: hawthorn (Crataegus oxyacantha) berry extract, taurine, garlic (Allium sativum) bulb, grape seed (Vitis vinifera) extract, grape skin (Vitis vinifera) extract, N-acetyl-L-cysteine, alpha-lipoic acid, soy (Glycine max) isoflavones, tocotrienols, L-Arginine (as L-arginine HCl), L-Carnitine (as L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12-12-05

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

### ENZYMATIC THERAPY®

&  
PHYTOPHARMICA®

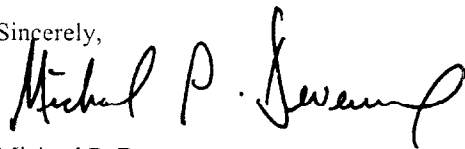
825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and a middle initial "P." in between.

Michael P. Devereux  
Chief Operations Officer